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ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

July 28, 2014

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

Pursuant to Rules X and XI of the U.S. House of Representatives, the committee is investigating the handling of select agents by federal laboratories. In particular, the committee is examining whether the Food and Drug Administration (FDA) complied with federal select agent regulations with regard to dangerous pathogens discovered at an FDA lab on the National Institutes of Health (NIH) campus, and whether the FDA's oversight of its laboratories on the NIH campus is adequate.

Recently, workers from the FDA discovered six vials of smallpox in a cold storage room in an FDA lab, located in Building 29A on the NIH campus. It appears these vials are about six decades old and were sitting in a cardboard box. Subsequent testing of the samples from two of the six vials showed the smallpox virus was still viable. Since smallpox was declared eradicated in the early 1980s, world health authorities believed that the only smallpox samples were safely stored at the Centers for Disease Control and Prevention (CDC) in Atlanta, and the Vector Institute at Novosibirsk, Russia. This was also reportedly the first time unaccounted-for smallpox samples were discovered since storage of smallpox samples was limited to CDC and the Vector Institute.

In addition to the smallpox vials, the FDA disclosed last week that the FDA workers also found 12 boxes and 327 vials holding an array of other pathogens, such as dengue, spotted fever, influenza, and Q fever. The discovery of these select agents in a cold storage room raises very serious questions about the NIH's ability to control, secure, and account for dangerous biological materials on the NIH campus and ensure compliance with federal select agent regulations.

To assist the committee's inquiry, please respond to the following questions and provide the following documents and information by August 15, 2014:

1. The smallpox samples and the other discovered vials of pathogen are dated well before 1972. The lab facility where these vials were discovered was reportedly transferred from the NIH to the FDA in 1972. Did the NIH transfer the ownership of the biological samples to the FDA? If yes, provide copies of documents related to the transfer of ownership of biological materials or samples in the labs. If not, were these vials still legally the property of the NIH? Provide the legal basis for the conclusion.

2. Has the FDA ever had a Memorandum of Understanding (MOU) with, or including, the NIH relating to the FDA laboratories on the NIH campus? If so, provide copies of any MOUs since the 1972 transfer or around the time of the 1972 transfer.

3. Have the FDA laboratories in Building 29A ever been inspected by the NIH? If so, please provide copies of any inspections conducted since 2002.

4. Have the FDA laboratories in Building 29A ever been inspected by the CDC and/or the Department of Agriculture's Animal and Plant Health Inspection Services (APHIS)? If so, please provide copies of any inspections conducted since 2002.

5. Have the FDA laboratories in Building 29A ever been inspected or audited by another federal agency or any other kind of external review group? If so, please provide copies of any inspections or audits conducted since 2002.

6. Provide a list of all FDA laboratories in Building 29A prior to June 1, 2014 with the associated area of research.

7. Did the FDA have a responsibility to account for all select agents being stored in FDA lab facilities on the NIH campus?

8. Has the FDA conducted any inventory checks of select agents of any lab in Building 29A, including the FDA labs?

9. Provide a list of FDA officials responsible for overseeing the FDA labs on the NIH campus.

10. Did the FDA ever conduct an inventory check accounting for all select agents at FDA labs on the NIH campus after 9/11 and the anthrax mailings? If not, why not?

11. Please identify all instances of discovery of select agents in unregistered locations at FDA since 2002. Include the dates, the locations, identity of the select agents, and actions taken.

12. Provide all e-mails in possession of Dr. Karen Midthun, the Director of FDA's Center for Biologics Evaluation and Research (CBER), relating to inventory checks of biological materials (including select agents) and/or laboratory animals at any FDA lab in Building 29A from January 1, 2010 to the present.

13. Provide all e-mails to or from any FDA director of an FDA lab in Building 29A relating to inventory checks of biological materials (including select agents) and/or laboratory animals at any FDA lab in Building 29A from January 1, 2010 to the present.

Your prompt assistance is appreciated. An attachment to this letter provides additional information on how to respond to the committee's request. If you have any questions, please contact Alan Slobodin of the committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

Joe Barton
Chairman Emeritus

Marsha Blackburn
Vice Chairman

Michael C. Burgess, M.D.
Vice Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations